IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	)	MDL No. 1:13-md-2419-FDS
This Document Relates to: All Cases	)	Judge Rya W. Zobel

DEFENDANT AMERIDOSE LLC'S REPLY IN SUPPORT OF ITS MOTION TO PROCEED WITH FDA-AUTHORIZED DESTRUCTION OF RECALLED PRODUCT (Leave of Court granted on 10/16/2014, NECC MDL Doc. 1492)

Defendant Ameridose LLC, through counsel and with leave of this Court, files this Reply in support of its Motion to Proceed with the FDA-Authorized Destruction of Recalled Product (NECC MDL Doc. 1090) and in opposition to the Tennessee Clinic Defendants' Response to the same (NECC MDL Doc. 1449). By agreement of the parties, the controlled substances portion of the Recalled Product has already been destroyed. What is now at issue is the destruction of the balance of the Recalled Product.

I. INTRODUCTION

Only the Tennessee Clinic Defendants oppose the destruction of Ameridose's recalled drug products[1] and, in doing so, misdirect the Court about the issue before it. This is not a

[1] No formal objection to Ameridose's Motion to Destroy was initially filed. Insight Guided Pain Management, a Virginia defendant in multiple cases, had no objection Ameridose's request to destroy the recalled drug products. Defendant UniFirst Corporation expressed various concerns, but ultimately agreed to abide by whatever agreements Ameridose reached with the PSC and the Tennessee Clinic Defendants between April and August 2014.

general discovery issue – there is no outstanding discovery or failure to respond to any. *See* Tennessee Clinic Defendants' Response ("TC Defts.' Resp."), NECC MDL Doc. 1449, pp. 1-3. The issue raised in Ameridose's Motion is much narrower than the Tennessee Clinic Defendants represent: Ameridose seeks an order from this Court allowing it to proceed with the FDA-approved destruction of recalled drug products. The primary reason why this destruction should be permitted is that any testing of this product would have no relevance to this litigation whatsoever. The product at issue in this litigation is methylprednisolone acetate ("MPA"), which was compounded and dispensed by NECC. Almost every complaint, and every PSC subpoena, motion, and every submission to this Court emphasizes that fact, including the PSC's past status reports. *See, e.g.,* NECC MDL Doc. 1005. It is undisputed that Ameridose LLC had absolutely nothing to do with the product - MPA – the drug allegedly responsible for the 2012 fungal meningitis outbreak. Thus, MPA is not part of Ameridose's recalled drug products.

Second, in addition to lack of relevance, any testing of the recalled products could not possibly produce a reliable source of evidence in this case. These recalled products are well beyond their expiration date. As a result, there are no tests that can reliably be performed to determine the condition they were in before they reached their expiration date.

Beyond relevance and reliability concerns, there are significant cost issues involved here. Ameridose has been forced to cease operations. It is in the process of selling its assets. It cannot continue to bear the costs of storing the recalled drug products. If the Court concludes that the recalled drug products cannot be destroyed and should be held for possible testing by the Tennessee Clinic Defendants, they should bear those costs.

II. LEGAL ARGUMENT

A. Testing of Ameridose's Recalled Drug Products Is Not Likely to Lead to the Discovery of Admissible Evidence.

1. Testing the recalled product will not lead to evidence relevant to the Tennessee Clinic Defendants' defense of the claims asserted against them.

Tests of Ameridose's products – which are not at issue in plaintiffs' complaints or any claims by the Tennessee Clinic Defendants – have no potential to yield relevant evidence. As pointed out in Ameridose's original memorandum, Doc. 1090, and as verified in the product recalls of both Ameridose and NECC, the two companies served different markets and made different products. More specifically, there is no dispute that MPA was not an Ameridose product. The two companies produced products in separate facilities. Although NECC and Ameridose were located at the same address from 2006 to 2009, they never shared the same space. Since 2009, more than three years before NECC compounded and distributed the MPA at issue, the two companies were at separate locations. The fact that there were separate facilities when the alleged contamination occurred is very important to the relevance inquiry since one of the Plaintiffs' key allegations is contamination of the clean room at NECC. See Adversary Complaint, case 12-19882 NECC Bankr. Doc. 94; Am. Master Compl. Against UniFirst and Liberty, NECC MDL Doc. 546.

The leading case on relevance on these facts is In re Richardson-Merrell, 97 F.R.D. 481, 484 (S.D. Ohio 1983). That case involved alleged injuries from a drug known as Bendectin. Plaintiffs sought discovery about other drugs made by the defendant. The court denied a request for discovery on matters relating to other products not at issue in the litigation as "beyond the scope of discovery." *See also* Fed. R. Civ. P. 26(b)(1). Beyond general relevance principles, this Court recently limited discovery that might be directed to Ameridose only to evidence which is "relevant to the prosecution, or defense, of claims against defendants other than the Estate Parties or Insider Settling Parties." Order Limiting Discovery, NECC MDL Doc. 1482, p. 3.

The Tennessee Clinic Defendants have not asserted any cross-claims or third-party claims against Ameridose, thus they are not entitled to pursue discovery against Ameridose "to see if Mr. Cadden was able to properly carry out his oversight obligations at Ameridose." TC Defts.' Resp., NECC MDL Doc. 1449, p. 3. The essence of the claims against the Tennessee Clinic Defendants is that they knew or should have known their supplier of MPA, NECC, had problems. But the Tennessee Clinic Defendants fail to explain how testing a different company's products helps them defend against the core claims asserted by plaintiffs or how it would be relevant to any allocation issue.

In addition, testing the recalled drug products inventory cannot lead to relevant evidence because there can be no proximate causation between the recalled drugs and any harm suffered by plaintiffs or, by extension, any claim or defense of the Tennessee Clinic Defendants. After two years of litigation one would think that, if such a connection existed, an enterprising plaintiff's lawyer would have unearthed from his client's medical records some evidence of harm from an Ameridose product. Yet no Plaintiff has sued over a specific Ameridose product and no Plaintiff has alleged harm from a specific Ameridose product. There is no CDC or FDA evidence in the medical literature or on their websites that an Ameridose product caused fungal meningitis in any patient in the United States. It is therefore logical that no Ameridose product is the proximate cause of harm alleged in this MDL. So, what relevance would such product testing have?

The Tennessee Clinic defendants suggest the recalled drug product inventory should not be destroyed because testing it might somehow shed light on the amount of control Barry Cadden had over compounding products at Ameridose. *See* TC Defts.' Resp., NECC MDL Doc. 1449, pp. 2-3. But testing of the recalled drug product inventory will only show certain --

unreliable -- scientific information about expired drug products other than MPA; it will not show who supervised its production.

2. Any results of tests performed on the recalled drug products will not be accurate and reliable because the recalled drug products have expired.

The recalled drug products' beyond-use dates ("BUD") and expiration dates have long-since passed, almost ensuring that testing of any of the 252,000 units contained in 67,000 boxes will yield inaccurate, irrelevant, and inadmissible results. *See* Affidavit of Ingrid Martin, Doc. 1090-1, ¶ 15. The BUD, a date assigned by the pharmacy (Ameridose, in this case) for a preparation they prepare, is the date after which a admixture cannot be administered. *See* USP 797, Pharmaceutical Compounding – Sterile Preparations, attached as Exhibit A; *see also* Kienle, Patricia C., RPh, MPA, FASHP, "Understanding Beyond-Use Dating for Compounded Sterile Preparations," Pharmacy Purchasing & Products Magazine, March 2007, pp. 1-5, attached as Exhibit B. An admixture's beyond-use date "identifies the time by which the preparation – once mixed – must be used before it is at risk for chemical degradation, contamination, and permeability of packaging." *Id.* at p. 1 (Ex. B). Testing of such material is pointless. It would not yield reliable evidence.

B. The Tennessee Clinic Defendants Should Bear the Costs of Continued Storage of Ameridose's Recalled Drug Products.

On October 8, 2014, Ameridose's counsel sent a letter to Tennessee Clinic Defendants' counsel explaining that Ameridose is in the process of selling all of its assets and will soon be forced to move the recalled drug product inventory to an FDA-approved, off-site storage vendor in order to lower the costs of continued storage and supervision. *See* October 8, 2014 Letter from

Ameridose's Counsel to TC Defts.' Counsel, attached as Exhibit C.[2] The costs of continued storage and supervision of Ameridose's recalled drug products are prohibitively expensive and contrary to the primary goal MDL Order No. 6 and the Plan Support and Funding Agreement: to create the largest possible asset pool to fund the settlement of as many claims as possible.

Even if the Court concludes that the recalled drug products may not be destroyed, this Court is still entitled to limit discovery where "the burden or expense of the proposed discovery outweighs its likely benefit," and to protect parties from "undue burden and expense" by shifting costs of discovery." Fed. R. Civ. P. 26(b)(2)(C)(iii), 26(c); *see also American Intern. Specialty Lines Ins. Co. v. NWI-I, Inc.*, 240 F.R.D. 401, 412 (N.D. Ill. Jan. 16, 2007) quoting *Sullivan v. Conway*, 1995 WL 573421, *1 (N.D. Ill. Sept. 27, 1995) (recognizing that the policy of broad discovery is counterbalanced by the ability to limit discovery requests that impose undue burden or expense); *Oppenheimer Funds v Sanders*, 437 U.S. 340, 358 (1970) (noting in *dicta* general rule that responding party bears cost of discovery, but also noting that Rule 26(c) permits courts to grant orders protecting parties from undue burden and expense by shifting costs of discovery).

C. The Tennessee Clinic Defendants' Proposal Regarding the Recalled Drug Products is Unrealistic.

After Ameridose filed its Motion, the Tennessee Clinic Defendants made inquiries and the parties began to discuss the issue. Ameridose offered to produce a CD containing 37,000 lines of data relating to the recalled drug products, and the Tennessee Clinic Defendants immediately accepted.[3] *See* April 24, 2014 Letter from Ameridose's Counsel to TC Defts.'

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[2] Ameridose is in the process of selling its assets pursuant to and as contemplated by the Plan Support and Funding Agreement that has been approved by the U.S. Bankruptcy Court in connection with the NECC bankruptcy. *See* Ex. C.

[3] Though the PSC initially declined Ameridose's offer to produce the CD containing the recalled drug product inventory, it later accepted and received a copy of the same. *See* May 15, 2014 Letter from Ameridose's Counsel to PSC's Counsel, attached as Exhibit E.

Counsel, attached as Exhibit D. The parties discussed several options for preserving the recalled drug products, including the proposal outlined in the Tennessee Clinic Defendants' Response. *See* TC Defts.' Resp., NECC MDL Doc. 1449, p. 4. This proposal called for retaining selected portions of the Recalled Product. Ameridose thoughtfully considered the proposal but explained to the Tennessee Clinic Defendants that it was not feasible for many reasons, including:

- The recalled drug products currently sit – and have been sitting – in the boxes in which they were returned by customers (*see* June 19, 2014 E-Mail from Ameridose's counsel to Tennessee Clinic Defendants' Counsel, attached as Exhibit F);
- The almost 67,000 boxes of recalled drug products sitting on 111 pallets are not organized by drug product, and because of that, it would take substantial man-hours to go through the pallets, boxes, boxes within the boxes, and spreadsheets to even locate the drugs at issue (*Id.*, Ex. F); and
- There is no way to know until the recalled drug products are found, opened, and measured whether there remains enough of any one recalled drug product to properly test according to the United States Pharmacopeia (USP) requirements (*Id.*, Ex. F).[4]

For the past six months, Ameridose has engaged in good faith efforts to resolve this matter while it continues to incur significant costs to store the expired recalled drug products. Ameridose's latest offer, as outlined in its letter of October 8, 2014, provides the Tennessee Clinic Defendants with reasonable access to the recalled drug products for a limited time at Ameridose's expense, or an extended period of time at the Tennessee Clinic Defendants' expense. If it is not allowed to destroy the recalled drug products, Ameridose should not be required to do any more than what has been offered.

[4] To conform to the USP 71 requirements for sterility testing, the tests must refer back to the size of each batch from which the recalled drugs came – which, in this instance, would require the monumental task of comparing the recalled inventory with the manufacturing records concerning hundreds to perhaps thousands of distinct drug batches. *See* USP 71, attached as Exhibit G.

III. CONCLUSION

For all reasons set forth above, Ameridose should be permitted to destroy the balance of its recalled drug products. In the alternative, the Tennessee Clinic Defendants should be ordered to pay storage costs for those recalled drug products.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 20, 2014, a copy of the foregoing **Defendant Ameridose LLC's Reply Brief in Support of its Motion to Proceed with FDA-Authorized Destruction of Recalled Product** was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

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